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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,203

08/18/2003

Jeffrey E. Stahmann

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EXAMINER

DINGA, ROLAND

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

04/29/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/643,203	<b>Applicant(s)</b> STAHMANN ET AL.	
	<b>Examiner</b> ROLAND DINGA	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/22/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 61-73,75-93,98-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-73,75-93,98-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 61-93 and 99-104 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Florio (US 2004/0002742)

Regarding **claim** 61 and 98-104, Florio discloses a medical device, comprising: a detector system (244 or 246) configured to detect patient conditions [see fig.2]; a disordered breathing detection system (238) coupled to the detector system and

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configured to detect disordered breathing [see fig.2]; a therapy control system (220 ) coupled to the disordered breathing detection system (238) and the detector system (244 & 246) configured to deliver a cardiac electrical therapy to mitigate the disordered breathing [see fig.2], the therapy control system comprising :and a therapy delivery system (240,240) coupled to the therapy control system and configured to deliver the adapted therapy to the patient, wherein at least one of the detector system (244 & 246) includes an implantable component [see fig.2]. Florio discloses in [para0065] administer a pacing therapy to treat sleep apnea and apply different types of pacing therapies on a patient to determine which therapies are effective at minimizing sleep disturbance. Florio also discloses in [para.0066] a process 800 for evaluating different pacing therapies in regards to their impact on sleep disturbance. In para[0070], Florio discloses that different therapies are analyzed to determine which of the therapies is most effective at reducing the frequency and /or number of sleep disturbance events or it would have been obvious to one skill in the art to assess how effective the therapy is and then reduced the negative impact of the therapy in order to properly treat sleep apnea.

Regarding **claim** 62, at least two of the detector system (244 or 246), the disordered breathing detection system (238) include implantable components [fig.2].

Regarding **claim** 63, at least three of the disordered breathing detection system (238), the detector system (244 & 246) and the therapy delivery system

(240,245) include implantable components [fig.2].

Regarding **claim** 64, the therapy delivery system (240,245) includes implantable components [fig.2].

Regarding **claim** 65, detector system comprises a patient-internal sensor 244[see fig.2].

Regarding **claim** 67, the telemetry unit is capable of being used by the patient.

Regarding **claim** 68, the disordered breathing detection system (238) includes a wirelessly connected component (254 & 264)[see fig.2].

Regarding **claim** 69, the disordered breathing detection system (238) is inherently configured to detect a respiration pattern of one or more respiration cycles, determine one or more characteristics of the respiration pattern, and classify the respiration pattern as disordered breathing based on the one or more characteristics of the respiration pattern [fig.2].

Regarding **claims** 70-92, the therapy control system (220) is inherently configured to adapt the specified since the device allows reprogramming of the control system and thus is configured to be adaptable to whatever needs. In addition, no particular stimulation regimen is specified for the therapy or the needs of the particular patient thus one therapy make work for one patient and not another.

Regarding **claim** 66, Florio discloses the invention substantially as claimed but failed to disclose a patient-external sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have

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modified Florio device with the external sensor, since such a modification would provide the predictable results of having a less invasive and can be worn or used by the sleep apnea patient only at times when the intention or expectation is to sleep.

Regarding **claim** 87, Florio discloses the invention substantially as claimed but failed to disclose that the therapy control system is configured to adapt the therapy to mitigate hypopnea or mitigate Cheyne-Stokes respiration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Florio device to the therapy control system is configured to adapt the therapy to mitigate hypopnea or mitigate Cheyne-Stokes respiration since it is well known (e.g US2002/0193697, US2003/0153954) in the art.

Regarding **claim** 89, Florio discloses the invention substantially as claimed but failed to disclose that the therapy delivery system is configured to deliver bi-ventricular pacing therapy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Florio device to deliver bi-ventricular pacing therapy, since such a technique is well known (e.g.US6477420 ) in the art.

Regarding **claim** 93, Florio discloses that invention substantially as claimed but failed to disclose that the therapy delivery system is configured to deliver multi-site pacing. It would have been obvious to one having ordinary skill in the art at

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the time the invention was made to have modified Florio device to deliver multi-site pacing, since such a technique is well known (e.g.US6292693 ) in the art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 61-73,75-93 and 98-104 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROLAND DINGA whose telephone number is (571)270-3644. The examiner can normally be reached on Monday through Friday from 8:30am to 5:00pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571 272 4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROLAND DINGA/  
Examiner, Art Unit 3766  
04/23/2009

/Mark W Bockelman/  
Primary Examiner, Art Unit 3766